

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the Claims

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claim 27 is currently being amended. Support for this amendment can be found throughout the specification as-filed, including ¶ [0022]. No new matter is being added.

Claims 28-35 are being added. Support for these new claims can be found throughout the specification as-filed, including [0007], [0010], [0011], [0022], and [0040].

Upon entry of the foregoing amendments, claims 1-35 will be pending in this application, and claims 1-26 are withdrawn. Thus, claims 27-35 are pending and subject to examination on the merits.

II. Information Disclosure Statement

The Office Action acknowledges Applicants' Information Disclosure Statement (IDS) filed May 27, 2005. However, citation no. C227 "has been lined through since it has not been identified by author, title, publisher, date of publication, and relevant pages, as is required." Office Action at ¶ 2.

Applicants plan to file shortly an IDS listing C227 by author, title, publisher, date of publication, and relevant pages, and the references listed in C227.

III. Claim Rejections – 35 U.S.C. § 102

A. Bhardwaj *et al.*, J. CLIN. INVEST. 98:715-722 (1996) as evidenced by Hackstein *et al.*, BLOOD 100(3):1084-1087 (2002)

Claim 27 stands rejected under 35 U.S.C. § 102 as allegedly anticipated by Bhardwaj *et al.*, J. CLIN. INVEST. 98:715-722 (1996) as evidenced by Hackstein *et al.*, BLOOD 100(3):1084-1087 (2002). The Office Action cites Bhardwaj as disclosing “a culture (i.e. a composition) comprising ex-vivo purified dendritic cells and IL-12,” and Hackstein is cited for disclosing that “dendritic cells arise from CD34+ stem cells.” Office Action at ¶ 4. “It is noted that the term ‘therapeutic composition’ carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition.” *Id.* Applicants respectfully traverse this ground of rejection.

Bhardwaj fails to anticipate the claimed invention, because Bhardwaj does not teach or suggest a “therapeutic composition,” as discussed below.

“During patent examination, the pending claims must be ‘given their broadest reasonable interpretation consistent with the specification.’” MPEP § 2111 (citations omitted). However, “[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.” *Id.* This broadest reasonable interpretation is based on the “ordinary and customary meaning” claim terms would have to one of ordinary to skill in the art. 2111.01(II).

Here, one of skill in the art would not consider Bhardwaj as disclosing a “therapeutic composition,” as required by the present claims. Instead, Bhardwaj discloses a cell culture that has both IL-12 and dendritic cells, which are either infected with influenza or uninfected. These compositions were used to evaluate the role of IL-12 in generating cytolytic T lymphocyte (CTL) responses to influenza virus. Bhardwaj does not, however, disclose a “therapeutic composition.” One of skill in the art understand that a “therapeutic composition” is a composition suitable for administration to a patient for the treatment of some disease or condition. Paragraphs [0046]-[0055], for example, of the specification confirm this understanding of a “therapeutic composition” by describing how to make specific types of composition formulated for use in patients. These compositions are formulated so as to preserve the stability of the active agents while making the composition biologically compatible. One of

skill in the art would not consider administering Bhardwaj to a patient for a therapeutic purpose, because Bhardwaj's crude culture contains agents, such as impurities, antithetical to a "therapeutic composition." Accordingly, Bhardwaj does not teach or suggest the claimed invention.

The Office Action argues that "is noted that the term 'therapeutic composition' carries little patentable weight in the absence of evidence of a structural difference." Office Action at 3. However, "therapeutic composition" does suggest structural features to one of skill in the art. Specifically, a "therapeutic composition" must be suitable for administration to some patient. A crude cell culture does not satisfy this criteria. Accordingly, the term "therapeutic composition" distinguishes Bhardwaj from the claimed invention.

B. Kelleher *et al.* INT'L IMMUNOLOGY 10(6):749-755 (1998)

Claim 27 stands rejected under 35 U.S.C. § 102 as allegedly anticipated by Kelleher *et al.* INT'L IMMUNOLOGY 10(6):749-755 (1998). According to the Office Action, "Kelleher *et al.* disclose a culture (i.e. a composition) comprising dendritic cells and IL-12 (see pg. 750 in particular)." Office Action at 3. Applicants respectfully traverse this ground of rejection.

Kelleher fails to anticipate the claimed invention, because Kelleher does not teach or suggest a "therapeutic composition." Instead, Kelleher discloses cultures comprising dendritic cells. IL-12 was added to some of these cultures to determine "whether IL-12 administration during DC maturation altered cell numbers, phenotype and function." Kelleher at 749, right col. The dendritic cells were cultured in "RPMI 1640 (Dutch modification; Sigma, Poole, UK) supplemented with 10% FCS (Gibco, Paisley, UK), 100 U Penicillin (Gibco), 100 µg/ml streptomycin (Gibco), 2 mM glutamine (ICN Flow, Irvine, UK), 2 mercaptoethanol 10⁻⁵ M (Sigma)." *Id.* Such a culture medium would not be considered a "therapeutic composition" to one of ordinary skill in the art, because a "therapeutic composition" is a composition suitable for administration to a patient for the treatment of some disease or condition. Kelleher's culture of dendritic cells would contain a number of impurities rendering the medium unsuitable for delivery to a patient for the treatment of a disease or condition.

The Office Action argues that "the term 'therapeutic composition' carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the

composition.” Office Action at 3. However, the term “therapeutic composition” does convey structural information, as discussed above in Section III(A). Specifically, the term conveys to one of skill in the art that the composition is formulated for administration to a patient, and a crude cell culture does not satisfy this requirement.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

C. U.S. Patent No. 6,017,527 to Maraskovsky *et al.*

Claim 27 stands rejected under 35 U.S.C. § 102 as allegedly anticipated by U.S. Patent No. 6,017,527 to Maraskovsky *et al.* According to the Office Action, Maraskovsky “teaches a therapeutic composition comprising dendritic cells in conjunction with cytokines (see column 11 in particular).” Office Action at 3. Applicants respectfully traverse this ground of rejection.

Maraskovsky does not anticipate claim 27, as presently amended, because Maraskovsky does not teach or suggest a composition “wherein the antigen presenting cell is not loaded or pulsed with antigens.” Maraskovsky specifically teaches that its dendritic cells should be “exposed to an antigen one wishes to elicit an immune response against and allowed to process the antigen (this procedure is sometimes referred to in the art as ‘antigen-pulsing’).” Maraskovsky at col. 1, ll. 64-67 (emphasis added); *see also* col. 11, ll. 4-47. Maraskovsky makes clear that this antigen-pulsing is necessary to perform before the cells are administered to a patient. *See, e.g.*, col. 1, l. 67 – col. 2, l. 3. The antigen presenting cells of the claimed invention, on the other hand, are “not loaded or pulsed with antigens.” This represents a significant advantage over Maraskovsky, because it avoids the time and effort needed to identify antigens and load the APCs with the antigens, such that they are presented by the APCs. Thus, Maraskovsky does not teach or suggest the claimed invention.

CONCLUSION

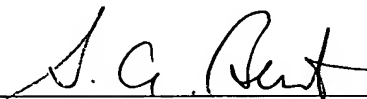
Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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